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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,334	05/12/2005	Jean-Max Huet	MART0890US	3598

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EXAMINER
BOUCHELLE, LAURA A

ART UNIT	PAPER NUMBER
3763	

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05/27/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/562,334	HUET, JEAN-MAX	
	Examiner	Art Unit	
	LAURA A. BOUCHELLE	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 May 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☒ Claim(s) *2-8* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/3/10 has been entered.

Claim Objections

2. Claim 4 is objected to because of the following informalities: Claim 4 recites, "keeping two lugs applied against one." It appears as though the claim should read "against one another". Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 (and thus all claims depending therefrom) includes a new limitation, "said device comprising a housing for said chamber." This amendment is not supported. Nowhere in

the originally filed disclosure is a housing for the chamber disclosed, nor is there a disclosure supporting said device - "said device" referring to an anti-stick device - comprising a housing for a chamber.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claim 1 recites "said device comprising a housing for said chamber." "Said device" refers to an anti-stick device for feeding a chamber implanted under the skin. It is unclear how the device that cooperates with a chamber also includes the housing for the chamber. It appears that applicant is attempting to claim a combination of the anti-stick device and the implanted chamber. However, the claims are drawn only to the subcombination of the anti-stick device and the phrase "for feeding a chamber implanted under the skin" in the preamble is an intended use limitation modifying the anti-stick device.

Claim Rejections - 35 USC § 103

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

9. Claims 1, 5, 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huet (EP 1 116 493 A1) in view of Brierley et al (US 5,116,324) in further view of Reid (US 6,755,805).

10. Huet discloses:

11. An anti-stick device capable of maneuvering an injection needle through the skin for feeding a chamber implanted under the skin. The limitation “for safely maneuvering an injection needle through the skin for feeding a chamber implanted under the skin" in claim 1 is considered to be an intended use limitation. The device of Huet, as will be discussed below, meets the structural limitations of the claimed device in such a way as to be able to perform the function of feeding a chamber implanted under the skin.

12. The needle being bent and having a perforating distal branch 17 and a proximal feed branch 18 which forms a bend with the perforating branch (see Fig. 1), said device comprising a needle-holding panel F, a base panel D, and a covering panel A forming a wall. See Fig. 1 annotated and included below.

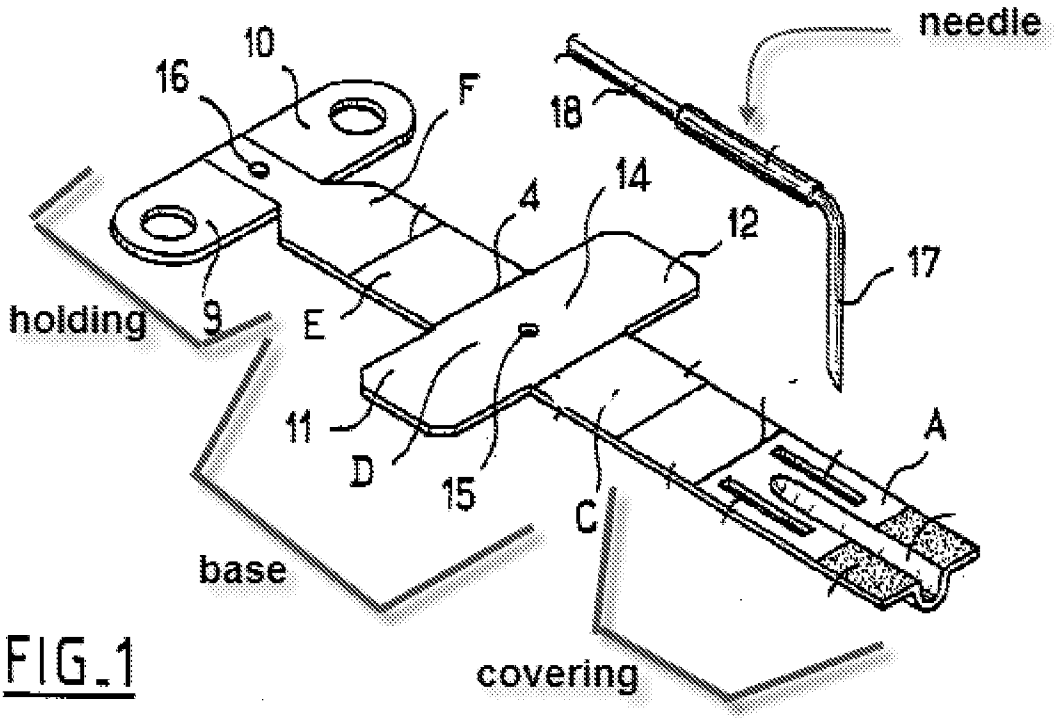

FIG.1

13. Said panels allowing said wall to be brought into a configuration in which said needle-holding panel is folded down onto said base panel (Fig. 2) and in which said covering panel is folded down onto said needle-holding panel and fixed thereto (Figs. 5, 6, the panel is fixed by the lugs 9, 10 protruding though slots A, shown in Fig. 4). Figs. 4 and 6 are included and labeled below.

Needle holding panel is folded down onto base panel

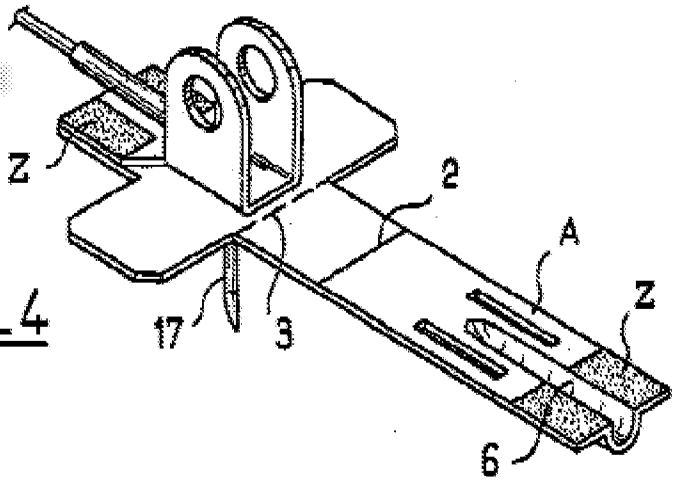

FIG_4

covering panel is folded down onto needle holding panel

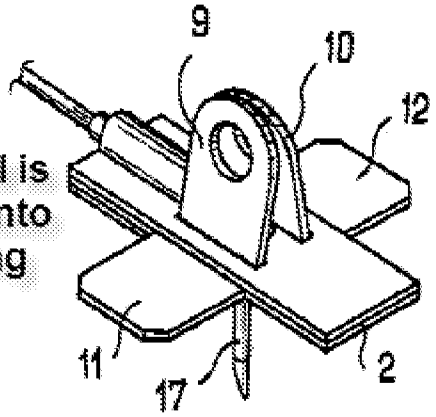

FIG_6

14. The panels can be brought into a configuration in which said needle-holding panel F and said covering panel A are fixed to one another and are spaced from said base panel D and form, between themselves and said base panel, a space which is sufficient to contain said distal branch 17 of said needle. See Fig. 10, annotated and included below.

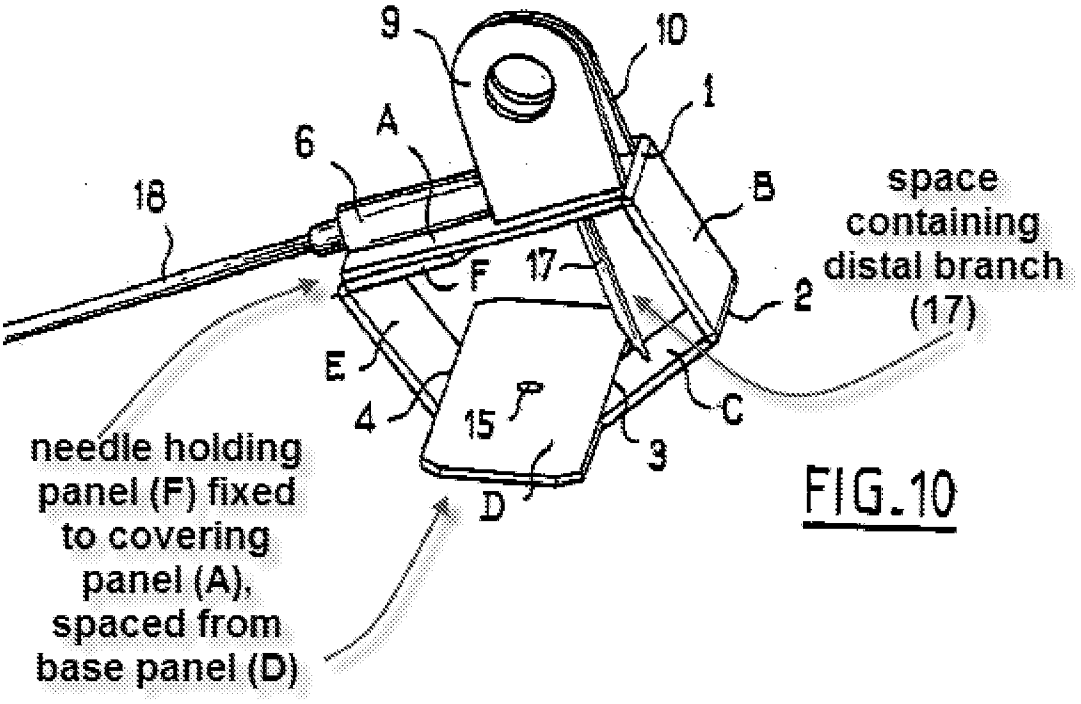

FIG. 10

15. Said base panel D and said needle-holding panel F having respective holes 15, 16 (Fig. 1) which permit passage of said distal branch of said needle and which coincide when said panels are joined (holes coincide Fig. 2, with needle passing through Fig. 3), whereby said distal branch can be introduced into said holes until said proximal branch 18 of said needle rests on said needle-holding panel (Fig. 3, needle rests on underside of needle holding panel F which is now folded over onto base panel D), said covering panel A covering said proximal branch of said needle when said covering panel is folded down onto said needle-holding panel (Figs. 5, 6).

16. Said base panel D having a central zone (the area near numeral 14 in Fig. 1) surrounding said hole 15 of said base panel and four lateral branches lying opposite one another in pairs and perpendicular to one another in pairs E and C, 11 and 12, said needle-holding panel F comprising two lateral lugs 9, 10 which can be lifted to permit manual gripping of said device at the time of puncture and at the time of withdrawal of said needle (see Figs. 6 and 9).

17. Claim 1 calls for the second pair of opposite lateral branches of said base panel to be capable of being bent by two fingers of one hand in order to press said second pair of branches toward the skin and said chamber for holding said chamber in place when the operator withdraws said needle. Huet discloses that as the lugs 9, 10 (Fig. 10 copied above) are gripped with one hand, the opposite lateral branches 11, 12 (labeled in Fig. 6 copied above) of the base panel D are pressed onto the skin with the other hand and the needle is removed (page 3, paragraph 0016 – for English translation, see US 6,663,604 col. 4, lines 57-65). Huet does not disclose that the pair of branches hold the chamber in place but this is considered to be a functional recitation. The branches of Huet are capable of being pressed down to hold whatever is underneath them in place.

18. Huet fails to disclose said base panel comprising a first pair of opposite lateral branches having a curvature for matching a contour of said base panel to a top of said housing for application of said base panel on the skin in line with said implanted chamber, and the needle holding panel having a curvature which is the opposite of the curvature of said first pair of branches so as to match the curvature of said first pair of branches when they are folded down onto said base panel. The limitation "for application of said base panel on the skin in line with said implanted chamber" is considered to be an intended use limitation. The device of Huet is

capable of being inserted into an implanted chamber. Huet discloses that in the installation position (needle holding panel folded over base panel) the device is secured to the skin by a piece of adhesive tape 20 (see fig. 8). Brierley teaches a device for securing a needle to the skin of a patient wherein the base of the device has a curved surface that conforms comfortable to the back of the hand and wrist area as well as most any other location of the body (col. 7, lines 39-43). This ensures that the needle is secure within the insertion site. It would have been obvious to one of ordinary skill in the art at the time of the invention to form the device of Huet including the base panel and the needle holding panel folded on top of it in the installation position with a curve to match the contour of the human body as taught by Brierley to increase patient comfort and the ensure that the needle is securely attached to the body.

19. Claim 1 also differs from Huet in calling for an implanted chamber. Reid teaches that needles such as the needle of Huet (i.e. bent "Huber" needles including needles extending from a base structure) are commonly used to fill and refill implanted chambers through pierceable septums (col. 1, lines 29-35). It would have been obvious to one of ordinary skill in the art at the time of invention to use the device of Huet in combination with an implanted chamber as taught by Reid because it is common practice in the medical art to refill an implanted chamber using a Huber needle that extends from a base.

20. Regarding claim 5, the covering panel A is shaped to constitute a channel 6 (shown best in fig. 1) that covers the proximal branch of the needle when the covering panel is applied to the needle holding panel F (see fig. 6, the needle is received in the channel). The limitation "channel able to receive an adhesive" is considered to be functional language. The channel 6 of Huet is capable of receiving an adhesive.

21. Regarding claim 6, Huet discloses that the device is formed from a flexible sheet of synthetic material (page 1, paragraph 0006 – for English translation, see US 6,663,604 col. 1, lines 65-67). The limitation "which has been cut out and pre-formed" is considered to be a product-by-process limitation. This claim is not limited to the manipulations of the recited steps, only the structure implied but the steps. The patentability of a product does not depend on its method of production. See MPEP 2113. Huet fails to explicitly disclose that the device is formed from plastic. However, one of ordinary skill in the art would recognize that plastic is a synthetic material that is commonly used in medical devices for its biocompatibility, ease of manufacture, ability to be sterilized, and low cost. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to form the device of Huet out of plastic because it is very common in the medical arts to use plastic to form devices that come in contact with the skin because it is biocompatible and sterilizable, as well as easy and economical to manufacture.

22. **Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Huet in view of Brierley in view of Reid as applied to claim 1 above, and further in view of Grabenkort et al (US 5,238,010).** Claim 3 calls for the opposite branches of the second pair of branches of the base panel to have reliefs. Huet fails to disclose that the opposite branches 11, 12 of the base panel D have reliefs. Brierley and Reid fail to teach such reliefs as well. Grabenkort teaches a device to be secured to the skin of a patient having lateral branches 22a, 22b that include reliefs (reliefs on the top of the branches as seen in Fig. 1 correspond to ribs on the bottom of the

branches as seen in fig. 3) to increase the flexibility of the branches (col. 3, lines 30-33) and thereby ensuring that the device may conform well to the body to be securely attached to the skin of the patient. It would have been obvious to one of ordinary skill in the art at the time of invention to modify the branches 11, 12 of Huet to include the ribs and reliefs of Grabenkort to increase the flexibility of the branches so that the device can conform to and be securely attached to various areas of the body and to patient's of all sizes.

23. **Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Huet in view of Brierley in view of Reid as applied to claim 1 above, and further in view of Frampton (US 3,538,915).** The limitation "means which cooperate for selectively keeping said two lugs applied against one another" is being interpreted as invoking 112 6th paragraph. While the recitation of "means for" is separated by the words "which cooperate" the claim can be read as "cooperating means for selectively keeping...". Huet fails to disclose such a means. Frampton teaches a device for holding a needle during infusion into a patient having lugs 22, 28 which have a first position parallel to the skin of the patient and a second position where they are in contact with one another for gripping by a user. The lugs include a means (projection 30 and hole 32) which cooperate with each other to keep the lugs applied against one another. See Figs. 4, 5. It would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Huet to include a projection and a hole on the lugs as taught by Frampton to keep the lugs applied together in the configuration seen in Fig. 7 of Huet so that the lugs can be readily and evenly gripped by the user to ensure that the needle is removed from the skin vertically to prevent patient discomfort.

24. **Claims 7, 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huet in view of Brierley in view of Reid as applied to claim 1 above, and further in view of Rosato et al (US 5,951,522).** Claim 7 calls for the device to comprise a pouch in which said wall is laid substantially flat. Claim 8 calls for the needle and a cap for shielding a beveled edge of the needle to be contained within the pouch. Rosato teaches a Huber needle device having an anti-stick device similar to that of Huet. Rosato teaches that the device is contained within a package in a flat configuration (col. 6, lines 14-16, fig. 6). The sharp beveled end of the needle is covered by a protective cap 31 while in the package (col. 6, lines 19-20). It would have been obvious to one of ordinary skill in the art at the time of invention to provide the device of Huet in a package as taught by Rosato so that the device remained sterile during shipping and storage as is a necessity in the medical field to prevent the risk of infection and contamination. It also would have been obvious to one of ordinary skill in the art at the time of invention to provide a cap for the needle as taught by Rosato to prevent the needle from puncturing the package during shipping and storage which would render the package and the device non-sterile and therefore unsuitable for use.

Allowable Subject Matter

25. Claims 2, and 3-8 when they depend from claim 2, are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

26. Claim 2 calls for the device to include a disk formed from hard plastic material on the first pair of branches on the base panel. The term “very hard" in the context of the claim and the

device as a whole, is interpreted to mean that the needle cannot penetrate the material under force generated by a typical person. Huet fails to disclose such a plastic disk. Knotek (5,531,704) teaches a needle puncture protection device have a needle and a panel configuration similar to that of Huet but further including a hard plastic wall 30 with a relief prevents slipping of the tip of the needle. However, there is no motivation to provide a disk of such material to the base panel of Huet.

Response to Arguments

27. Applicant's arguments filed 5/3/10 have been fully considered but they are not persuasive.

28. Applicant argues that Huet fails to disclose the two opposite lateral branches of the panel have a curvature for application of these branches to the skin so that the base panel is in line with the implanted chamber. The examiner relies upon Brierley to teach that it is obvious to form a device that contacts the skin having a curved surface so that the device closely conforms to the body for increased stability. The limitations regarding the implantable chamber are interpreted to be intended use limitation. The device of Huet having curved panels as taught by Brierley is capable of being in line with an implanted chamber or any other feature of interest.

29. Applicant argues that Huet fails to disclose a chamber residing in a housing having a top to which the profile of the base of the panel imparted by the curvature of the lateral branches is matched for securing the chamber when the base panel is urged against the skin. Again, the device of Huet in view of Brierley is capable of securing a chamber when the panel is urged against the skin. Furthermore, as taught by Reid, it is well known in the art to use devices such as the one of Huet to refill implanted chambers.

30. Applicant argues that Huet fails to disclose that the lateral branches are capable of being bent at will under pressure exerted by two fingers. The examiner disagrees. The branches of Huet are formed from a thin material and therefore are capable of being bent by two fingers if sufficient force is applied.

31. Applicant argues that Huet fails to disclose that the needle holding panel and the covering panel have a curvature which is the opposite of the curvature of the pre-curved branches to as to match the curvature of the pre-curved branches when they are folded down onto the panel. The examiner relies again upon Brierley to teach this feature. One of skill in the art would recognize that the teaching of Brierley of a device having a curved configuration applies to the device in the installation position. Because of the way the branches of Huet are folded upon one another in the installation position, upon unfolding they would necessarily be curved in opposite directions.

32. Applicant argues that Huet is not intended to be used to maneuver a needle for feeding a chamber implanted under the skin. The examiner argues that this is an intended use limitation and the device of Huet is capable of maneuvering a needle into an implanted chamber. Furthermore, Reid teaches that devices similar to that of Huet are commonly used to refill implantable chambers.

33. Applicant argues that the limitations of claim 1 provide for a number of things including, easily applying device in alignment with a chamber implanted under the skin, holding the chamber in place, and permitting withdrawal of the needle from the chamber. All of these assertions constitute a recitation of the intended use of the claimed invention. Such a recitation must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is

capable of performing the intended use, then it meets the claim. As laid out in the body of the rejection above, there is no structural difference between the claimed invention and the prior art.

34. Applicant argues that the device of claim 1 imparts an elastic deformation to the needle during its withdrawal from the chamber so that when it exits the opening it automatically moves away form the opening for protecting the operator. This is not a claimed feature. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

35. Applicant argues that Brierley disclose no match between the housing an implanted chamber and the curvature of a protector for stabilizing the chamber. The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA A. BOUCHELLE whose telephone number is (571)272-2125. The examiner can normally be reached on Monday-Friday 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 517-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Laura A Bouchelle
Examiner
Art Unit 3763

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Examiner, Art Unit 3763